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Food Safety And Inspection Service
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AUDIT REPORT FOR HONG KONG

FEBRUARY 18 THROUGH 22, 2000

December 13, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Hong Kong's poultry inspection system from February 17 through 22, 2000. The establishment certified to export meat/poultry to the United States (U-1) was audited. This was a processing establishment; no slaughter operations were conducted.

The last audit of Hong Kong's meat inspection system was conducted in March 1998. The same establishment was audited: it was acceptable. Only minor deficiencies were reported at that time; they had been corrected. Several new deficiencies were identified, regarding non-performance of pre-shipment reviews, species verification, and an equivalent of FSIS;s Non-compliance Record.

Only poultry products, for which the poultry meat is produced in establishments in the United States, are eligible for export to the U.S.

During calendar year 1999, this establishment exported 729,277 pounds of poultry products to the U.S. One lot containing eleven pounds of product was rejected at the U.S. port of entry for a labeling defect.

PROTOCOL

This on-site review was conducted in three parts. One part involved an on-site visit to the establishment. The second was a visit to the laboratory performing analytical testing of field samples for the national residue testing program and microbiological testing of final products. The third entailed a meeting with various Hong Kong national poultry inspection officials to discuss oversight programs and practices, including enforcement activities.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, (2) animal disease controls, (3) residue controls, (4) processing controls, and (5) enforcement controls. Hong Kong's inspection system was assessed by evaluating these five risk areas, with a special emphasis on Hazard Analysis – Critical Control Point (HACCP) Systems, Sanitation Standard Operating Procedures (SSOPs), and the testing program for *Listeria monocytogenes*.

During the on-site establishment visit, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Except as noted below, effective inspection system controls were found to be in place in the establishment. Details of audit findings, including compliance with the requirements for a HACCP program, SSOPs, and the testing program for Listeria monocytogenes are discussed later in this report. Among the deficiencies found during this new audit were the following:

1. Pre-shipment reviews were not being performed.

2. No samples were being analyzed for species verification.

3. The inspection officials had not developed a document equivalent to the Noncompliance Record.

Entrance Meeting

No entrance meeting was held. The Headquarters Audit was conducted on the day of the exit meeting.

Headquarters Audit

1. The organizational structure of the inspection service had undergone change since the last FSIS audit. The poultry inspection system was now under the control of the Food & Environmental Hygiene Dept; formerly it was the Hygiene Division of the Dept. of Health. This was effective January 1, 2000.

2. The auditor examined a selection of centralized records that were maintained in the headquarters offices; among the documents audited were copies of the periodic internal supervisory reviews, the 1999 results and the 2000 plan for the national residue testing program, and an outline of the 2000 monitoring program for *Listeria monocytogenes* for finished products produced at Establishment U-1.

Government Oversight

The inspector assigned to the establishments certified by Hong Kong as eligible to export poultry products to the United States was a full-time employee of the Food and Environmental Hygiene Department (FEHD), receiving no remuneration from either industry or establishment personnel.

Establishment Audit

The single establishment certified to export poultry products to the United States at the time this audit was visited for an on-site audit. Both FEHD inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audit

During the laboratory audit, emphasis was placed on the application of procedures and standards that are equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories, if any (none were being used for the national residue testing program),
2. Intra-laboratory quality assurance procedures, including sample handling, and
3. Methodology.

The Government Laboratory, located in the Ho Man Tin Government Offices, where all residue testing was performed, was audited on February 21, 2000. Effective controls were found to be in place for sample handling, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, recovery frequency, corrective actions, and storage and use of chemicals. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). Hong Kong's National Residue Testing Plan for 1999 was being followed, and was on schedule.

Several aspects of the residue laboratory's program did not meet the expectations usually required in countries that are certified to export meat and/or poultry products to the U.S; however, it must be noted that these requirements were designed to establish controls in countries in which meat animals and/or poultry are slaughtered, and the resulting meat and/or poultry meat is subsequently either exported directly to the U.S. or used in products which are then exported to the U.S. This is not the case in Hong Kong. No poultry slaughtered either in Hong Kong or in any country other than the United States is used in any product eligible for export to the United States. The residue testing that is done for this establishment is performed not only on the frozen poultry meat imported into Hong Kong from United States establishments, but also on shrimp, which are imported from Viet Nam and Taiwan, as well as non-meat ingredients (vegetables and spices) and packaging materials.

Intra-laboratory check samples were being performed at intervals of once every three months for all classes of residues except PCBs (these were being done every six months). FSIS usually expects these check samples to be performed monthly.

The laboratory had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities. Results of analyses were being reported simultaneously to the government and the establishment.

Routine microbiological testing of final products for *Listeria monocytogenes* was being performed (and documented) monthly in the laboratory of the Pathological Institute of the Department of Health. There had been no positive results.

Establishment Operations

For the products eligible for export to the United States, Establishment U-1 was importing frozen poultry meat from poultry slaughter establishments within the United States and processing this poultry meat, together with shrimp imported from Viet Nam and Taiwan and various vegetables and spices, and cooking the resulting products.

SANITATION CONTROLS

Based on the on-site audits of the establishment, Hong Kong's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest control and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over-product ceilings and equipment; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product handling and storage.

Sanitation Standard Operating Procedures

The establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The Sanitation Standard Operating Procedures (SSOPs) were audited and found to meet the basic FSIS regulatory requirements.

ANIMAL DISEASE CONTROLS

No poultry meat from animals slaughtered in other than establishments within the United States were used in product eligible for export to the U.S.

RESIDUE CONTROLS

Hong Kong's National Residue Testing Plan for 2000 was being followed, and was on schedule. Adequate controls were in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER AND PROCESSING CONTROLS

No slaughter operations were conducted. Hong Kong's inspection system had controls in place to ensure compliance with requirements regarding ingredients identification, formulations, packaging materials, label approvals, processing equipment and records, and post-processing handling.

HACCP Implementation

All establishments approved to export meat/poultry products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Establishment U-1's HACCP system was evaluated according to the criteria employed in the U.S. domestic inspection program (the data collection instrument used accompanies this report as Attachment B), and was found to meet the basic FSIS regulatory requirements, with the following exceptions:

1. No formal documented pre-shipment document reviews were being performed. The requirement for this had not been understood. The auditor explained the requirement in detail, during both the exit meeting in the establishment and with the inspection officials in the country exit meeting. The requirement was understood, and FEHD officials assured the auditor that they would ensure that it would be implemented immediately.

2. Several illegible corrections were found in the daily Critical Control Point documentation. This was discussed, and immediate steps were taken to ensure that all personnel maintaining the daily documentation are instructed to keep any corrections legible.

Testing for Generic *E. coli*

The establishments was not required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, since there were no slaughter operations and no ground meat was being produced.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the FEHD inspection system controls (control of inspection samples, shipment security, monitoring and verification of establishment programs and controls, inspection supervision, and documentation) were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

One of the inspection officials' responsibilities is a system for documenting noncompliance by the establishment with elements of their HACCP and SSOP systems. This involves a written document containing a description of the noncompliance, a reference to the regulation or requirement that was not met, signature of the inspection official, signature of the establishment official receiving the document, and a written response by the establishment official. These are to be kept on file and available. This requirement had not been understood; the inspection officials agreed to develop and employ an equivalent noncompliance record promptly.

Testing for *Salmonella* Species

The establishments was not required to meet the basic FSIS regulatory requirements for *Salmonella* testing, since there were no slaughter operations.

Species Verification Testing

At the time of this audit, species verification was not being performed routinely: the Hong Kong inspection officials believed Hong Kong was exempt from this requirement. The auditor checked whether the following five conditions for exemption were being met:

1. *Carcasses and products are transported between establishments in devices which are sealed with a tamper-detectable inspection seal applied by the Inspection Service at the originating establishment and broken by the Inspection Service at the receiving establishment.*

   Products were not transported between establishments. This has been the only establishment certified to export to the U.S. for many years.

2. *Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service control.*

   There were no brands or sealing devices in need of security control by the inspection service. Blank health certificates were kept in the headquarters offices, and filled out as necessary from there.

3. *Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.*

   This condition was met.

4. *Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.*

No slaughter operations have ever been conducted at this facility; this condition was met in the processing areas.

5. *Product must be exported to the United States in a cargo container sealed by the Inspection Service.*

   This was not being performed. Any seals applied to cargo containers were being applied by the transport companies; however, all product leaving the establishment was cooked and contained in hermetically sealed packages.

The Hong Kong officials, subsequent to this audit (in April, 2000), have applied officially for an exemption from the species testing requirement. As of the writing of this report, this request has not been reviewed by an FSIS equivalence team.

Monthly Reviews

The internal audits in Hong Kong were being conducted by the Senior Health Inspector (Mr. Li Ka Kei). Mr. Li was supervised by Mr. Tang Kam-chuen, Chief Health Inspector (Foods).

No specific method was used for selecting the review date of the establishment, but the date varied from month to month. The internal audit program was applied only to the export establishment. The internal audits were completely unannounced, and were conducted at least once, and sometimes twice per month.

Copies of the internal audit reports were kept in a locked drawer in the inspection office in the establishment and were also maintained on file at inspection headquarters. They were being maintained on file for a minimum of six years.

If the establishment were to be found to fail to comply with U.S. requirements during an internal audit, it would be immediately delisted for U.S. export, and any products produced as of the start of business on the day of the audit would be ineligible for access to the U.S. market. Establishment U-1 has never been found to be unacceptable either by U.S. auditors or by internal reviewers.

To gain an accurate overview of the effectiveness of inspection controls, the FSIS auditor requested that the review of the establishment be led by the inspection official who normally conducted the periodic reviews for compliance with U.S. specifications. The auditor observed and evaluated the process. After observing the internal reviewer's activities in the field, the auditor was confident in his professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Hong Kong's internal review program as a whole.

Enforcement Activities

Compliance activities and enforcement issues in Kong Kong were regulated by Public Health & Municipal Services Ordinance, Chapter 132, Laws of Hong Kong; Part 5 dealt with provisions for food safety & Hygiene. There was also a Food Business Regulation that governed handling of foodstuffs in food factories, and an Imported Game, Meat, and Poultry Regulation. An Antibiotic Ordinance regulated and monitored the use of veterinary drugs

and withholding times. Local farmers were, within the next year, to be required to apply for special permits to be able to purchase and use certain over-the counter drugs, such as antibiotics.

At the time of this audit, there were no legal provisions in place to prevent anyone convicted of food industry violations from holding positions of authority in export meat establishments.

Exit Meetings

A meeting with Hong Kong's poultry inspection officials was held in the headquarters offices of the FEHD on February 22. In attendance were the new head of the inspection service, Dr. Yuen Sun-on, Senior Superintendent (Food Surveillance and Certification); Chu Siu-man, Field Officer I (Veterinary Public Health Section); Dr. Mabel Yeung, Senior Medical Officer (Food Incidents Response & Management); Dr. Jai Man-Ho, Jeffrey, and Dr. Tai Hing-fung, Veterinary Officers (Veterinary Public Health Section); Tang Kam-chuen, Food Surveillance and Labeling; Johnny Y.K. Chu, Food Scientist; Caroline Y.L. Yuen, Agricultural Specialist, Agricultural Trade Offices, American Consulate General; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. The deficiencies regarding the lack of implementation of pre-shipment document reviews and the illegible corrections were discussed, and the Hong Kong officials promised prompt monitoring to ensure that corrective actions were immediate and effective.

2. The findings from the laboratory audit were discussed. Dr. Yuen expressed concern regarding the expense that would be incurred should FSIS advise expanding the laboratory's quality assurance programs to meet the requirements the International Audit Staff is usually instructed to expect in countries certified to export meat and/or poultry products to the United States, especially in the area of the monthly intra-laboratory check samples (see comments under Laboratory Audit, page 3). The auditor noted

   that, as mentioned earlier in this report, no poultry meat other than that received from establishments within the United States is used in products exported to the U.S. The matter has been referred to the International Policy Division for equivalency determination.

3. The auditor explained in detail the purpose and content of a Noncompliance Record. The FEHD officials expressed their intention to develop an equivalent document promptly.

CONCLUSION

The inspection system of Hong Kong was found, on the whole, to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. The establishment was acceptable. The deficiencies encountered during the on-site establishment audit were adequately addressed to the auditor's satisfaction or were discussed in the country exit meeting, and were to be addressed promptly by the FEHD officials.

Dr. Gary D. Bolstad (Signed) *Dr. Gary Bolstad*
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used included the following statements:

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1. The establishment has a written SSOP program	Yes
2. The procedure addresses pre-operational sanitation.	Yes
3. The procedure addresses operational sanitation.	Yes
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.	Yes
5. The procedure indicates the frequency of the tasks.	Yes
5. The procedure identifies the individuals responsible for implementing and maintaining the activities.	Yes
6. The records of these procedures and any corrective action taken are being maintained on a daily basis.	Yes
7. The procedure is dated and signed by the person with overall on-site authority.	Yes

Attachment B

Data Collection Instrument for HACCP Programs

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. This systems in Hong Kong was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.	Yes
2. The establishment had conducted a hazard analysis.	Yes
3. The analysis includes food safety hazards likely to occur.	Yes
1. The analysis includes the intended use of or the consumers of the finished product(s).	Yes
2. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.	Yes
3. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.	Yes
8. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.	Yes
8. The plan describes corrective actions taken when a critical limit is exceeded.	Yes
9. The HACCP plan was validated using multiple monitoring results.	Yes
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.	Yes
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.	Yes
12. The HACCP plan is dated and signed by a responsible establishment official.	Yes

NOTE: 1. No formal documented pre-shipment document reviews were being performed. The requirement for this had not been understood. The auditor explained the requirement in detail, during both the exit meeting in the establishment and with the inspection officials in the country exit meeting. The requirement was understood, and FEHD officials assured the auditor that they would ensure that it would be implemented immediately.

2. FEHB officials had not developed an equivalent of the FSIS Noncompliance Record, a written document containing a description of noncompliance, a reference to the regulation or requirement that was not met, signature of the inspection official, signature of the establishment official receiving the document, and a written response by the establishment official. This requirement had not been understood; the inspection officials agreed to develop and employ an equivalent noncompliance record promptly.